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| APPLICATION NO.             | FILING DATE                        | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|------------------------------------|----------------------|---------------------|------------------|
| 10/520,100                  | 01/04/2005                         | Masaya Tanaka        | 0020-5551PUS1       | 6992             |
|                             | 7590 09/15/201<br>ART KOLASCH & BI | EXAMINER             |                     |                  |
| PO BOX 747                  | CU VA 22040 0747                   | KASSA, TIGABU        |                     |                  |
| FALLS CHURCH, VA 22040-0747 |                                    |                      | ART UNIT            | PAPER NUMBER     |
|                             |                                    |                      | 1619                |                  |
|                             |                                    |                      |                     |                  |
|                             |                                    |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|                             |                                    |                      | 09/15/2010          | ELECTRONIC       |

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

|  |   | Application No.  | Applicant(s)   |  |  |  |
|--|---|--|----------------|--|--|--|
| Office Action Summary  |   | 10/520,100   | TANAKA, MASAYA |  |  |  |
|  |   | Examiner   | Art Unit       |  |  |  |
|  |   | TIGABU KASSA   | 1619           |  |  |  |
| Period fo  | The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply                                     |  |                |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |  |                |  |  |  |
| Status   |   |  |                |  |  |  |
| 1)   | Responsive to communication(s) filed on <u>06 Ju</u>  | lv 2010  |                |  |  |  |
| ·  | •   | action is non-final.   |                |  |  |  |
| 3)   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |  |                |  |  |  |
| ت (۵   | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.   |  |                |  |  |  |
|  | and a second and a second and a   | n parto Quayro, 1000 O.D. 11, 10   | 30 0.0. 210.   |  |  |  |
| Disposit   | ion of Claims   |  |                |  |  |  |
| 4)🛛  | Claim(s) <u>37-46</u> is/are pending in the application.  |  |                |  |  |  |
|  | 4a) Of the above claim(s) is/are withdrawn from consideration.  |  |                |  |  |  |
| 5)   | 5) Claim(s) is/are allowed.   |  |                |  |  |  |
| 6)🛛  | 6)⊠ Claim(s) <u>37-46</u> is/are rejected.  |  |                |  |  |  |
| 7)   | Claim(s) is/are objected to.  |  |                |  |  |  |
| 8)□  | Claim(s) are subject to restriction and/or  | election requirement.  |                |  |  |  |
| Applicat   | ion Papers  |  |                |  |  |  |
| 9)□  | The specification is objected to by the Examine   | r.   |                |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.   |   |  |                |  |  |  |
| <i>,</i> —   | Applicant may not request that any objection to the o   |  |                |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |  |                |  |  |  |
| 11)  | 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |  |                |  |  |  |
| Priority <b>ı</b>  | under 35 U.S.C. § 119   |  |                |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |   |  |                |  |  |  |
| 2) Notice 3) Infor   | et(s) se of References Cited (PTO-892) se of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) or No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ate            |  |  |  |

### DETAILED ACTION

### Formal Matters

Applicants' amendment filed on July 06, 2010 is acknowledged and entered. Claims 37-46 are pending. Claims 37-46 are under consideration in the instant office action. Claims 1-36 are cancelled. Applicant has amended instant claim 37 by incorporating a limitation reciting "a viscous reactant containing a carbonate and a thickener" in the second component of the reaction mixture.

# Moot Rejections/Objections

All rejections and/or objections of claims 1-36 cited in the previous office action mailed on March 04, 2010 are moot, because said claim(s) has/have been cancelled.

### Rejections Withdrawn

The rejection of claim 44 applied in the previous office action under 35 U.S.C. 112, second paragraph is hereby withdrawn as a result of applicant's claim amendment.

# Content of Interview

Applicant's attorney discussed about a possible claim amendment incorporating a thickener not only in the viscous material but also in the reactant. The examiners suggested that applicant must have support in the original disclosure for such an amendment. Additionally, the examiners also suggested with regard to the alleged improved properties stated in the declaration filed on July 16, 2009 applicant should provide evidence or convincing argument that the

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incorporation of the thickener both in the viscous material and the reactant is responsible for the improvement namely the suppression of bubbles.

# Rejections Maintained

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically taught or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 37-47 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al., (WO 99/24043) using (U.S. patent No. 6,689,339 as translation of WO 99/24043) in view of Gibbins et al., (WO 01/49258, which incorporates by reference Gibbins et al., US Patent 5928174 and Nangia et al., US Patent 5196190), for the reasons of record and the reasons set forth herein.

### Tanaka Declaration under 37 CFR 1.132

The declaration submitted by Masaya Tanaka on 07/16/09 is still found to be not persuasive and sufficient to overcome the rejections for the same reasons of record set forth in the previous Office Action. The examiner incorporates those rebuttal arguments by reference in this section as well, as they are equally applicable.

### Response to arguments

Applicant's arguments filed 07/06/10 have been fully considered but they are not persuasive.

Applicant argues that Tanaka '339 fails to disclose or suggest the present invention which requires a thickener in both the base agent (containing an acid and water) and the reactant (containing a carbonate).

This is not found persuasive because indeed Tanaka et al., clearly teach viscous compositions that contain a carbonate and a thickener together. For instance, Tanaka et al. teach in column 13 in examples 1-84 section Tables 1 to 7 show carbon dioxide-containing viscous compositions each preparing by mixing a carbonate-containing aqueous viscous composition

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and an acid wherein the production process is stated as carbonate-containing aqueous viscous compositions are prepared combining thickeners, purified water and carbonates as shown in Tables 1 to 7. Solid acids are used as they are or after being pulverized or dissolved or dispersed in a suitable solvent. Liquid acids are used as they are or after being diluted with a suitable solvent. The obtained carbonate-containing aqueous viscous composition and the acid are mixed to provide a carbon dioxide-containing viscous composition. The examiner noticed that Tanaka et al., clearly teach the carbonate containing viscous composition as described above also contains a thickener as exemplified by compositions described in Tables 1 to 7. Additionally, Tanaka et al., teach that in addition, the carbonate-containing aqueous viscous composition, acid-containing aqueous viscous composition and aqueous viscous composition may respectively be prepared from a preparation such as a thickener-containing granular (fine-granular or powdery) carbonate or the like, a thickener-containing granular (finegranular or powdery) acid or the like and a thickener-containing granule (fine-granule or powder) or the like (column 8, lines 41-48) another strong evidence that the carbonate containing reactant can also contain a thickener. Although Tanaka et al., teach clearly thickeners can be incorporated in the carbonate containing reactant and also with the acid as set forth above, applicant seems to suggest that Tanaka et al. do not show the incorporation of thickeners in the carbonate containing reactant in the examples. In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); Schenck v. Nortron Corp., 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). A prior art reference

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must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Applicant did not consider the prior art as a whole as evidenced by the teachings set forth above from Tanaka et al.

Applicant also asserts that it is also clear from a proper interpretation of Tanaka '339 that the described compositions provide for substantial generation of carbon dioxide in the form of bubbles. For example, as noted at column 14, lines 12-29, embodiments of the described compositions were evaluated with respect to the relative increase in carbon dioxide bubble generation which is described as the "foaming properties" of the evaluated compositions.

This is not found persuasive because of the rebuttal arguments set forth in the previous office action that the use of materials such as sponge and gauze would necessarily suppress the formation of bubbles by a mechanism of trapping them within the pores.

Applicant also argues that the generation of carbon dioxide occurs outside the gauze or sponge in Tanaka et al. versus inside the nonwoven cloth.

This is not found persuasive because this limitation is addressed by Gibbins et al. Furthermore, the examiner reminds applicant that the rejection is based on the combined teachings of Tanaka et al., and Gibbins et al., However, applicant resorted to attacking the references individually. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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Applicant also argues that the other cited reference, i.e. Gibbins '258, fails to make up for the deficiencies noted with respect to Tanaka '339. Gibbins '258 fails to address enhancement of percutaneous absorption of carbon dioxide by employing an appropriate acidic environment as in the present invention. Gibbins '258 also fails to disclose the presence of a thickener in both a base agent and reactant as in the present invention. Gibbins '258 is further removed from the present invention than Tanaka '339, such that all of the above-noted distinctions over Tanaka '043/'339 also apply to Gibbins '258. Consequently, even if Gibbins '258 is hypothetically combined with Tanaka '339, the resulting hypothetical combined disclosure would still fail to described or suggest the features of the present and claimed invention. Therefore, the above-noted rejection based on the combination of these references must also be withdrawn.

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This is not found persuasive because applicant is resorting to attacking the references individually while the rejection is based on the combined teachings of Tanaka et al., and Gibbins. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For Gibbins et al., (WO 01/49258) to be a proper prior art Gibbins et al., (WO 01/49258) does not have to teach each and every limitation s of applicant's claimed invention Gibbins et al., (WO 01/49258) is incorporated in the rejection to remedy the deficiency of Tanaka et al., for not teaching the viscous material being initially impregnated in an elastic polymeric three-dimensional network structure prior to reacting it with the carbonate. Gibbins et al., indeed teach the incorporation of acid into the matrix followed by addition of carbonate to generate carbon dioxide within the matrix which is

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the deficiency of Tanaka et al. Gibbins et al., (WO 01/49258) teach matrices such as polyacrylamide and a non-gellable mucopolysaccharide, which are polymeric three-dimensional network structures, being used to trap a gas generated after a reaction between two different reactants (page 18, lines 7-11). Gibbins et al., (WO 01/49258) teach that the gas bubbles are generated by the permeation of the second reactant added to the formed matrix that contains the first reactant (page 18, lines 13-14). The reaction between the two reactants in situ results in the liberation of gas which is **entrapped within the matrix** (page 18, lines 14-16). Acryderm®, used by Gibbins et al. to form the matrix is water absorbent, elastic, and oxygen permeable polymeric material (page 29, lines 22-23 and line 26). The matrix of Gibbins et al., is, therefore, an elastic polymeric three dimensional network structure. Gibbins et al., (WO 01/49258) also teach the possibility of incorporating an active agent with the second reactant, which is similar to the viscous composition in the instant application (page 18, lines 10-11). Gibbins et al., (WO 01/49258) also mention that the composition can be added to the **preformed matrix either** simultaneously or sequentially, for perfusion within the matrix (page 21, lines 20-23). The formed matrix is then placed in the presence of the second reactant for the reaction to proceed so as to form the gas bubbles (page 18, lines 14-16). Gibbins et al., (WO 01/49258) also specifically teach the possibility of generating of carbon dioxide gas within the matrix by reacting an acid catalyst which is incorporated in the matrix followed by the perfusion of the matrix with a carbonate (page 15, lines 10-12). The examiner respectfully disagrees with applicant's assertions because Gibbins is clearly related to the instantly claimed invention since Gibbins teaches matrices for the delivery of gases including carbon dioxide to tissues.

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Applicant also assert that the Examiner states that Gibbins '258 teaches the incorporation of acid into the matrix followed by addition of carbonate to generate carbon dioxide; but the teaching is limited to generate gaseous carbon dioxide in bubble form. The generated gaseous carbon dioxide will be entrapped in the closed cells of the matrix, and some of the gas will be dissolved in the cell wall that contains water. But the dissolved carbon dioxide in the cell wall and the entrapped carbon dioxide inside the closed cells easily escapes in the air because the matrix of Gibbins '258 has no mechanism to prevent the generated carbon dioxide from escaping. It is common knowledge that water-dissolved carbon dioxide easily escapes in the air in a very short period of time if there is no mechanism of suppressing bubble formation of the generated carbon dioxide.

This is not found persuasive because of the same rebuttal arguments set forth above because the formation of bubble based gaseous carbon dioxide can be easily trapped and contained within the sponge, gauze, or other network structures that are described by both Tanaka et al., and Gibbins et al. as set forth above.

Applicant has not demonstrated how his product is patentably distinct from the cited prior arts nor do the claims as currently written distinguish the instant invention over the prior arts. In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

# Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne P. Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from

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either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call

Tigabu Kassa 9/10/10

800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/ Primary Examiner, Art Unit 1647